ENVIRONMENTAL ASSESSMENT

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BIOLOGICAL DEFENSE RESEARCH PROGRAM AT THE ARMED FORCES INSTITUTE OF PATHOLOGY

Prepared by:

United States Army Medical Research and Materiel Command

Fort Detrick
Frederick, MD 21702

With technical assistance from:
Beaver Schaberg Associates, Inc.
3620 Ingleside Road
Shaker Heights, OH 44122

Under subcontract to:
Science Applications International Corporation
Frederick, MD 21703

Contract Number DAMD1 7-93-C-3141

April 24, 1996

DEPARTMENT OF THE ARMY
U.S. Army Medical Research and Materiel Command (USAMRMC)
Walter Reed Army Institute of Research (WRAIR)
Washington, DC 20307-5100

ENVIRONMENTAL ASSESSMENT

Biological Defense Research Program at the Armed Forces Institutes of Pathology

Prepared by:
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March, 1996

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EXECUTIVE SUMMARY

The proposed action (preferred alternative) is the continuation of the Biological Defense Research Program (BDRP) activities currently performed at the Armed Forces Institute of Pathology (AFIP) in Washington, DC. These BDRP activities involve research studies directed towards gaining a comprehensive understanding of immunology responses to *Brucella melitensis* as part of efforts to develop a vaccine for use in humans.

The principal conclusions of this environmental assessment (EA) are: 1) continuing the *Brucella* research activities, the preferred alternative, will not result in a significant impact on the environment, 2) these activities will result in a significant benefit to the United States by protecting soldiers from the possible use of a potential biological warfare agent, and 3) moving these research activities to another location (Alternative II), or ceasing operations (Alternative III, No Action), will not significantly alter the environmental impact of this project.

This EA was prepared in accordance with guidance provided in Army Regulation (AR) 200-2 *Environmental Effects of Army Actions*, dated December 23, 1988, implementing the National Environmental Policy Act (NEPA) (42 USC 4321-4347). This EA, *Biological Defense Research Program at the Armed Forces Institute of Pathology*, was researched and prepared by the AFIP with technical assistance from Beaver Schaberg Associates, Inc. under subcontract to Science Applications International Corporation, for the U.S. Army Medical Research and Materiel Command (USAMRMC) under Government Contract Number DAMD17-93-C-3141.

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PURPOSE AND NEED FOR THE PROPOSED ACTION

The objective of this EA is to determine the extent and significance of potential environmental impacts associated with the conduct of the BDRP-funded activities at the AFIP. Activities at the AFIP are conducted under several programs including the BDRP.. The BURP is funded by the U.S. Congress and implemented through the Department of Defense (DoD) by the Department of the Army (DA). The mission of the BDRP is to discover and develop medical countermeasures (e.g., vaccines and drugs) to protect U.S. forces from the effects of biological or toxin agent weapons, to diagnose and treat diseases resulting from exposure to such agents, and, through such activities, to deter, constrain, and defeat the hostile use of such agents. In meeting its mission, the BDRP funds research conducted at the AFIP to develop a vaccine against brucellosis,, a bacterial disease caused by *Brucella* which has been identified as a possible biological warfare threat The production of vaccines against potential biological warfare agents such as *Brucella* involves the use of animal and nonanimal models and requires implementation of specific safety standards and practices including the use of biosafety level 3 (BL-3) facilities (HHS Publication No. (CDC) 93-8395, 1993).

This EA is prepared in accordance with AR 200-2 (32 CFR 651) which provides guidance for the preparation of EAs for Army actions, including adherence to requirements set forth in NEPA and implementing regulations, To reduce redundancy with previously prepared documents and to meet the paper reduction requirements of the Council on Environmental Quality (CEQ) (40 CFR 1500-1508), this EA is tiered, in part, to earlier NEPA documentation. This approach entails referencing specific analyses, discussions, and conclusions of such documents without providing detailed discussion in the present EA.

There are two groups of documents relevant to this EA for tiering purposes. The first includes those reports and assessments related to the Walter Reed Army Medical Center (WRAMC) installation, of which the AFIP is a tenant, and the Walter Reed Army Institute of Research (WRAIR) with which the AFIP collaborates on BDRP activities. These documents include Environmental Science and Engineering (1984); reports by Kise Franks & Straw (1990a, 1990b); and WRAIR EAs (1993a, 1993b, 1994). These documents provide information about the environmental setting of the AFIP. The WRAIR EA (1993a) also provides information pertaining to the conduct of other BDRP activities within the WRAIR.

The second group of documents pertains to the programmatic evaluation of the BDRP. A Final Programmatic Environmental Impact Statement (FPEIS) was prepared by the DoD in 1989 which examined environmental effects related to the BDRP. The Record of Decision (ROD) resulting from the BDRP FPEIS found that although certain aspects of this program are controversial, particularly those aspects relative to aerosol testing and the use of genetically engineered microorganisms (GEMs), the program remains unaltered because the analyses found no evidence of major negative environmental impacts (BDRP FPEIS, 1989). Various public and government groups were involved with the preparation and completion of the BDRP FPEIS. Dialogues and multidisciplinary, multidimensional analyses

indicated that public concerns expressed at the local level were programmatic in nature and not directly to specific sites within the BDRP found that any potential adverse impacts to the human environment associated with the continuation of BDRP research efforts were minimal. In this EA, the BDRP activities ties performed at the AFIP are examined for their potential to cause significant adverse environmental impacts.

DESCRIPTION OF THE PROPOSED ACTION

The proposed action described here for the AFIP is the conduct of a BDRP-funded research project with *Brucella* organisms. This bacterial pathogen is a potential biological warfare agent; therefore, the research and development of an effective human vaccine against human pathogenic strains *(B. melitensis,, B. suds, B. cants, B. abortus)* the U.S. military forces with protection from this threat This EA examines only the BDRP activities conducted at the AFIP..

The AFIP

The 1994 AFIP Annual Report describes the mission of the AFIP as threefold -education, and research." The AFIP began in 1862 as the Army Medical Museum which was founded for the purpose of research and for the training of Army medical officers. In 1893, the Museum founded the Army Medical School, now known as the WRAIR.. The American Registry of Pathology (ARP) was founded at the Museum in 1922 for the purpose of facilitating cooperation with civilian medical practitioners. The Army Medical Museum became the Army Institute of Pathology in 1946 at which time it became the central pathology laboratory of the U.S. Army. In 1949, the Institute became the AFIP and its role expanded to include civilian, as well as military pathology.

The AFIP maintains a central laboratory of pathology for consultation and diagnosis of pathologic tissue for the DoD, other federal agencies, and civilian pathologists. Among its many roles, the AFIP conducts pathology research; provides instruction in pathology and related subjects; trains armed forces enlisted personnel in pathology techniques; provides and maintains educational materials; maintains the National Museum for Health and Medicine of the AFIP; and contracts with the ARP for cooperative medical, educational, and research enterprises between the Institute and civilian entities. Among the services which the AFIP provides are surgical pathology and autopsy consultation to pathologists worldwide, medicolegal investigations, and a veterinary pathology response team for emergency situations involving animals. Some of the ongoing work at the AFIP includes DNA analysis; forensic toxicology; molecular diagnostics; breast cancer, cardiovascular disease, parasitic and infectious diseases research; and environmental toxicologic pathology.

The Board of Governors of the AFIP includes the Assistant Secretary of Defense for Health Affairs, DoD; the Assistant Secretary for Health, Department of Health and Human Services; the Surgeons General of the Army, Navy, and Air Force; the Chief Medical Director for the Department of Veterans Affairs; and a former AFIP Director.

The AFIP is organized into five Centers: Center for Advanced Pathology (CAP); Center for Clinical Laboratory Medicine; Center for Medical Support Services; Center for Administrative Services; and the Center for Publication, Automation, Education & Museum. The CAP is further organized into 23 departments specializing in pathology, veterinary pathology, environmental toxicology, legal medicine, and radiology (AFIP, 1994).

The BDRP-funded *Brucella* vaccine work examined in this EA within the AFIP Department of Infectious and Parasitic Diseases Pathology, Division of Microbiology (AFIP 1994; Hadfield,, 1995a). The Brucella vaccine program is conducted under a cooperative agreement with the WRAIR and the AFIP. The terms of the collaboration between the AFIP and the WRAIR are detailed in a Memorandum of Understanding signed by the parties in the fall of 1992 (see Appendix A). The conduct of BDRP activities performed at the WRAIR previously underwent environmental review (WRAIR, 1993a).

The AFIP is a tenant organization on the campus of the WRAMC in Washington, DC. The WRAMC is bounded by 16th Street, Alaska Avenue, Georgia Avenue, Fern Street, and Aspen Street (Figure 1). The AFIP is located in Building 54.

General Safety

All activities of a hazardous nature performed by either civilian or military personnel at work sites within the AFIP are governed by the *AFIP* Safety Program (AFIP Regulation 385-10) The *AFIP Safety* Program implements all applicable federal, state, local, DoD, Headquarters DA, WRAMC, and USAMRMC requirements, polices, and practices. Compliance with AFIP Regulation 385-10 is mandatory for all civilian and military personnel engaged in activities at the AFIP.

AFIP Regulation 385-10 defines the responsibilities for safety program implementation including the organization and oversight of a safety committee. The AFIP Safety Committee is chaired by the Executive Officer and co-chaired by the Chief, Logistics Department and meets no less than monthly. Among the permanent members of the committee are the AFIP Safety Officer, the three Assistant Safety Officers, floor safety monitors, chemical hygiene officer, radiation protection of officer and the Chief of the Division of Laboratory Animal Medicine.

In accordance with AFIP Regulation 385-10 department chairpersons and division chiefs maintain and annually review written safety procedures. It is the responsibility of supervisors to ensure that all personnel comply with safety regulations and standing operating procedures (SOPs). Supervisors investigate and report accidents and injuries and maintain records of actions taken when reports of safety hazards are received.

A Memorandum of Agreement (MOA) exists between the WRAMC, WRAIR, AFIP, and the District of Columbia Office of Emergency Preparedness to ensure coordinated fire, police, and health emergency support services (see Appendix B). Signed in May, 1993, the MOA describes the emergency support services provided by WRAMC and the

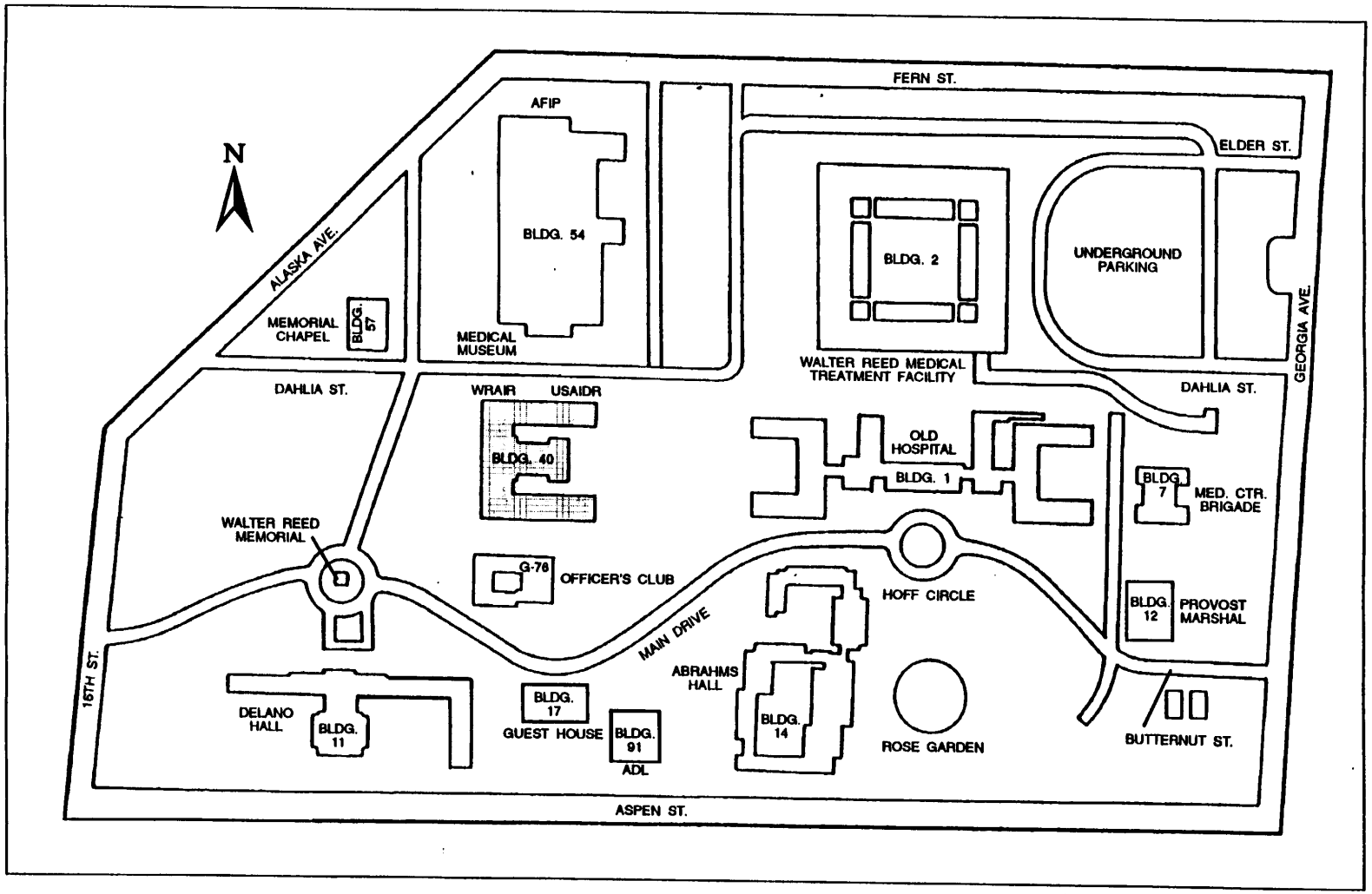

Figure 1. Location of the AFIP

District of Columbia Office of Emergency Preparedness to the WRAIR the event of an accident, incident or other emergency situation. In addition, the MOA describes the responsibilities of each of the listed entities with regards to incident and accident reporting, compliance with regulatory and statutory guidelines, and the coordination of emergency response efforts.

Brucella

The bacterium *Brucella is* an animal pathogen and the ecologic agent of human brucellosis also referred to as Bang's disease, Undulant fever, Malta fever, or Mediterranean fever. Brucellosis is caused by one of four *Brucella* species and its distribution is worldwide. Brucellosis is acquired by direct contact with the secretions of body fluids and aborted fetuses of infected animals or by ingesting contaminated animal products (e.g., milk or milk products). In rare instances brucellosis may be transmitted from person to person (Kaufmann, 1995; Merck & Company, Inc., 1987).

Naturally-acquired cases of brucellosis are rare in the U.S. because of high levels of food sanitation and animal brucellosis control programs. However, historically Laboratory infections have been commonly reported (Harding and Liberman, 1995; Sewell, 1995). In a laboratory setting, brucellosis may be acquired by 1) the entry of the organism through microscopic breaks in the skin or through accidental sticks with a contaminated needle or other sharp object; 2) inhaling organisms from contaminated air; 3) direct contact of contaminated materials with mucous membranes; or 4) oral intake of the organism.

Brucella is a virulent (readily able to cause disease) organism, and human infection may result from exposure to less than 10 organisms (Harding and Liberman 1995; Kaufmann, 1995). The virulence and pathogenicity of *Brucella* vary by species. *Brucella ovis* and *B. neotomae* do not cause disease in humans, while *B. suis, B. abortus, B. melitensis,* and *B. cants* can result in human disease. *B. suis* and *B. melitensis* are mere likely to cause severe disease than are *B. abortus* and *B. cants* (Hadfield, 1995b). Clinical symptoms of brucellosis may include fever, intermittent or continuous chills, night sweats, headache, weakness, anorexia, weight loss, muscle and pint pain, and depression (Kaufmann and Boyce, 1995). Because the symptom of brucellosis may be confused with those of other illnesses, an infection may be difficult to recognize unless a known or possible exposure to *Brucella* organisms has occurred. Disease symptoms may become evident within days of exposure or may develop gradually over several months. Infections are effectively treated with antibiotics, and mortality is low (less than 2 percent) even in untreated cases of brucellosis (Kaufmann and Boyce, 1995).

Brucella are destroyed by disinfectant, sunlight, and heat. Under venous environmental conditions, some *Brucella* spp. can persist in soil, dust, or water for 1 to 2 months (Hadfield, 1995b, 1995c; Mitscherlich and Marth, 1984).

Handling and Use of *Brucella*

The brucellosis vaccine development work conducted at the AFIP requires the use of viable *Brucella* organisms. Work with infectious agents is conducted according to guidelines for laboratory biological safety described in the publication entitled *Biosafety In Microbiological and Biomedical Laboratories* published by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) (CDC/NIH, 1993). These guidelines recommend the levels of laboratory practices and techniques, facilities, and equipment necessary to contain infectious organisms of varying degrees of pathogenicity and virulence, and their products. These measures minimize risks to human health and the environment. Federal guidelines for laboratory work involving the testing of biological products are described in the Food and Drug Administration (FDA) Regulations for Good Laboratory Practices (GLP) (21 CFR 58).

The CDC and the NIH have established four biosafety levels (BL) for conducting laboratory operations with infectious agents and/or their toxins. These biosafety levels are described in the CDC/NIH guidelines. BL-1 practices, safety equipment, and facilities are appropriate for facilities in which work involves defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. BL-2 practices, safety equipment, and facilities are appropriate for facilities performing work with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Work with indigenous or exotic agents that have serious or lethal consequences if inhaled requires BL-3 containment. BL-4 practices, safety equipment, and facilities are required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Under these guidelines, the laboratory director is responsible for determining the appropriate biosafety level based upon "the virulence, pathogenicity, biological stability, route of spread, and communicability of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the endemicity of the agent; and the availability of effective vaccines or therapeutic measures (CDC/NIH, 1993). The CDC/NIH guidelines include agent summary statements which provide guidance for the selection of appropriate biosafety levels and specific information on laboratory hazards associated with various agents (CDC/NIH, 1993).

Activities conducted at the AFIP for the BDRP must also meet the requirements set forth in 32 CFR Parts 626 *(Biological Defense Safety Program, Final Rule, AR* 385-69) and 627 *(Biological Defense Safely Program, Technical Safety Requirements,* DA Pamphlet 385-69). These regulations implement the recommendations detailed in the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories.* The potential for aerosol generation during work with *Brucella* requires BL-3 containment (Hadfield, 1995a).

> “The facilities, equipment and procedures applicable to clinical diagnostic, research, a production facilities in which work is performed with indigenous or exotic agents where potential exists for infection by aerosol, and the disease may have serious or lethal consequences It differs from BL-2 in that (1) more extensive training in handling pathogenic and potentially lethal agents is necessary for

laboratory personnel; (2) all plagues involving the manipulation of infectious material are corded within biological safety cabinets, other physical containment devices, or by personnel wearing appropriate personal protective clothing and devices; (3) the laboratory has special engineering and design features, including access zones, sealed penetrations and directional airflow (32 CFR 627).

The organisms used in the BDRP-funded activities include:

Brucella melitensis 16M
Brucella melitensis RM1
Brucella melitensis isolate
Brucella melitensis Rev1
Brucella abortus 2308
Brucella abortus RA1
Brucella abortus isolate
Brucella abortus strain 19
Brucella abortus RB51
Brucella abortus biotypes 1-7, and 9
Brucella abortus 2308 pUR E 201
Brucella abortus 2308 pUR E 198
Brucella abortus 2308 pUR 1<
Brucella suds
Brucella ovis
Brucella cants
Brucella neotomae

The AFIP Department of Infectious and Parasitic Diseases Pathology has developed a series of Operational Instructions (OIs), under the authority of AFIP Regulation 3810 and in accordance with CDC/NIH guidelines, that detail policy and procedures by which work with *Brucella* is conducted. Personnel are required to adhere to procedures described in OIs. The AFIP Safety Officer is responsible for conducting safety inspections. Supervisors are responsible for ensuring that personnel comply with applicable OIs. The OI entitled *Biocontainment Laboratory Operations, Biosafety Level 3* describes the policies and procedures for safe operation of the BL-3 laboratories and animal facilities including assignment of personnel; authorization for admittance; posting of signs; clothing; entry and exit procedures; personal operations; equipment and supplies; registration, storage, and transport of infectious organisms; and laboratory techniques (see Appendix C).

Physical Facilities

The AFIP physical facilities used for *Brucella* studies are located on the four and fifth floors of Building 54. These facilities have been designated as BL-3 facilities and as such signs are posted on all doors to indicate their BL-3 designation, the agent(s) in use within, and the appropriate individuals to contact in the event of an emergency. Access to the BL-3 laboratories is restricted to those personnel directly involved with the work. The laboratory is secured by lock when unoccupied. The BL-3 laboratories are kept locked at all times and the doors are magnetically controlled to prevent unauthorized entry. Entry into each BL-3 area is through a specially-designed halfway located immediately outside of the laboratory. In addition to these measures, which limit and control access into BL-3 work areas, there are offer measures in place that minimize the possibility of infectious organisms breaching the confines of the laboratory. These include sealing all surfaces in each laboratory and adjacent halfway with' epoxy paint, and all penetrations to the comes with silicone or over approved sealant; electrical outlets and switches are also designed to reduce the potential for contamination. Infectious or potentially infectious materials do not leave the BL-3 facility until rendered non-infectious by disinfection or autoclaving. For this

reason, autoclaves with two sets of doors are positioned within hallway areas so that one door opens to the outer "cleans.

The AFIP BL-3 laboratories are equipped with dedicated air handling system which maintain a constant negative pressure relative to areas outside of the laboratory and anteroom. Air leaving the BL-3 facilities is vented through high efficiency particulate air (HEPA) filters which remove 99.97 percent of particulate matter greater than or equal to 0.3 micrometers. Each room within this laboratory is under negative pressure relative to the inner hallway. All exhaust air generated from the air handling system is vented through HEPA fibers which are located on the roof of the building. There are no floor drains in the BL-3 facilities (Hadfield, 1995a).

The fifth floor BL-3 rooms include a laboratory and adjacent animal handling area which are used for work with mice and mouse tissues. The laboratory is equipped with a 6 foot laminar flow safety cabinet. Animal rooms within this area contain laminar flow animal cabinets and a laminar flow safety cabinet for handling animals and changing animal cages. The air from laminar flow cabinets is vented through HEPA filters which are located on the roof of the building. The fifth floor area is equipped with a redundant heating, ventilation, and air conditioning (HVAC) system to ensure that the required climate control is maintained at all times. Should the primary climate control system to this area fail, the secondary system automatically engages (Hadfield, 1 995a).

The fourth floor BL-3 laboratory also contains a 6 foot laminar flow cabinet in which all work with infectious or potentially infectious materials is conducted. The air stream leaving the laminar flow safety cabinet is vented through a HEPA-filtered exhaust vent. Centrifuges within the laboratory contain sealed rotors or sealed cups. Pipetting is conducted in the safety cabinet using automatic pipettes. Infectious materials are removed from the laboratory after sterilization.. Data generated within the laboratory are transmitted via electronic means to eliminate the need to remove paper from the containment suite of the electronic network c becomes nonfunctional, the paper on which data are written is taped to the inside of a laboratory window so that it can be copied onto a data sheet outside (Hadfield, 1995a).

The Department of Infectious and Parasitic Diseases Pathology OI, *Biological Safety Cabinet and Chemical/ Fume Hood Monitoring and Calibration Program,* describes the policies and procedures for certifying and monitoring biological safety cabinets and chemical fume hoods. Biological safety cabinets, including laminar flow animal containment devices are certified after installation, relocation, and annually. Chemical fume hoods are certified every six months. Written records of certification and testing are maintained by the AFIP medical maintenance department and dated certification stickers are placed on each cabinet. All fume hoods and biological safety cabinets are monitored daily and gauge readings are recorded as part of He quality assurance and quality control data for the area. Medical Maintenance is notified in He event that gauge readings vary more than 10 percent of the posted value.

The Department of Infectious and Parasitic Diseases Pathology OI, *Hydrogen Peroxide Vapor or Enclosure Sterilizer*, describes the correct procedure for safely and effectively sterilizing rooms, equipment, or enclosures with 32 percent hydrogen peroxide vapor. During this process, the space undergoing sterilization is sealed with tape and a sign is posted indicating the possible presence of hydrogen peroxide vapors. In addition, a Material Safety Data Sheet (MSDS) for hydrogen peroxide is posted. Prior to sterilization, biological and chemical indicator steps are distributed around the room and monitored for the effectiveness of the sterilization procedure.

BL-3 Operations

Prior to working in a BL-3 facility, each worker receives a safety briefing, donates a blood sample for the serum bank, and agreed to adhere to the required laboratory dress code (Hadfield, 1995b). Workers preparing to enter the laboratory change out of their street clothes into surgical scrubs. Within the laboratory, additional clothing requirements include use of an outer wrap around gown, face mask, gloves, and foot covering or shoes dedicated solely for use within the laboratory. Before exiting the laboratory, face mask, gown, and shoe coverings are discarded into a waste container dedicated for this purpose. Waste outer garments are autoclaved prior to removal from the laboratory (Hadfield, 1995a).

The *AFIP/ARP Bloodborne Pathogen Exposure Control Plan* implements 29 CFR 1910.1030 the *Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard.* The *OSHA Bloodborne Pathogen Standard was* developed to reduce occupational exposure to hepatitis B virus, human immunodeficiency virus, and other pathogenic agents potentially transmitted by blood and blood products. All personnel employed or contracted by the AFIP or ARP are required to comply with the standards and procedures of this plan. Methods of compliance entail engineering and work practice controls and the use of personal protective equipment. Engineering controls include the use of biological safety cabinets which ensure that personnel are physically isolated from biological hazards. Work practice controls include performing tasks using techniques which reduce the likelihood of exposure to biological hazards. The possibility of a biological hazard coming into contact with a worker's clothes, skin, eyes, or mouth is limited by use of personal protective equipment including face shields, gloves, clothing, masks, engineering controls (e.g., HEPA filtration) and laboratory practices.

The AFIP Department of Infectious and Parasitic Diseases Pathology OI, *Infected Animals - Housing and Handling* directs that cages housing infected animals be labeled to indicate the presence of infectious agents. Infected animals are housed in approved cages in laminar flow containment units. Signs are posted on rooms in which infected animals are housed. The signs indicate the required protective clothing, name of infectious agent, and the name and phone number of the principal investigator or other responsible person. Inoculation of infected animals is performed within biological safety cabinets or animal rooms. Animals inoculated with infectious agents are maintained in a manner which reduces the generation of aerosols from bedding and refuse. Animals are observed daily.

Dead animals are placed in approved, closed, plastic bags and marked as biohazards to transport to an autoclave, refrigerator, freezer, or necropsy area.

Animal containment suites are maintained in a clean and orderly fashion. Sinks and safety cabinets with drains tied to the central sewer system are flooded with disinfectant solution on each day of use. Suite decontamination procedures involve washing areas with disinfectant at the completion of experiments Gloves and masks or respirators are worn when cleaning freezers, refrigerators, and incubators.

The Department of Infectious and Parasitic Diseases Pathology OI enticed *Procedure for Routine Exchange of Supplies and Reagents and Transport of Cultures from the BL-3 Laboratory* describes the required procedures for disinfecting equipment, supplies, reagents and other items which cannot be disinfected by autoclaving prior to removal from the laboratory. This OI is in accordance with 49 CFR, DA and DoD regulations governing the transport of etiologic agents. Supervisors are responsible for training personnel in the proper techniques. Written documentation of the training is prepared by the supervisor and maintained for at least 3 years. The AFIP Safety Officer is responsible for ensuring that the procedures used meet or exceed local, state, and federal guidelines, and/or regulations.

If viable organisms must be transported out of BL-3 containment laboratories, the AFIP Safety Officer is notified and ensures that cultures are properly packaged and container surfaces disinfected. If organisms must be transported to facilities outside of the AFIP, they are packaged according to CDC/NIH 49 CFR, Department of Transportation, International Air Transport Association (Dangerous *Goods Regulations)* and BDRP regulations (32 CFR 326 and 327). Cultures are transported only by carriers which ensure the ability to constantly track materials (e.g., Federal Express).

Accident Reporting

Accidents occurring within the Division of Microbiology are reported to the Chief of the Division of Microbiology or AFIP Safety Officer and the Safety Monitor, Infectious- and Parasitic Diseases Pathology immediately The Chief, Division of Microbiology notifies the following individuals telephonically or electronically within three hours of confirming the accident.

Safety Officer AFIP	(202) 782-2693
Biosafety Committee Chairman	(202) 782-2652
Chairman, IPD	(202) 782-1849
Director, CAP	(202) 782-2503
Executive Officer	(202) 782-1660
Director, AFIP	(202) 782-2111
Safety Officer WRAIR	(202) 782-0955
Safety Officer, USAMRMC	(301) 619-2003

A written report from the individual experiencing the accident is submitted the same day as the occurrence of the accident. The report is investigated and a written submitted by the Chief, Division of Microbiology within 72 hours of the accident to the AFIP Safety Officer. The completion and distribution of accident reporting forms are described in AFIP Regulation 385-10 and AR 38540.

Waste Stream Management

AFIP Regulation 40-12 *(Waste Management Program)* provides direction in the management of wastes generated at the AFIP and applies to all personnel assigned to or employed by the AFIP or any personnel working in an AFIP facility. AFIP policy requires that all employees comply with federal environmental law, executive orders, and regulations; DoD Directive 4265.60, which promulgates the resource, recovery, and recycling program for solid and other wastes; and AR 2001 *(Environmental Policy and Enhancement),* which assigns responsibilities and establishes procedures for military solid waste management.

AFIP Regulation 40-12 requires waste to be segregated by category at the point of origin. All wastes generated within BL-3 laboratories and restricted areas are separated into general waste or other type of waste (regulated medical waste) at the site of origin.

General Solid Waste

General solid waste is waste that does not contain regulated materials such as infectious waste or hazardous chemicals. General waste such as garbage, rubbish, and nonregulated medical waste is placed into waste cans or clear waste bags and is managed and disposed of by normal waste disposal methods without pretreatment AFIP contracted housekeeping services remove and dispose of all general waste from non-restricted areas. Department personnel remove general waste from within restricted areas and place it in non-restricted areas for disposal by housekeeping services.

Regulated Medical Wastes

Regulated medical wastes (RM.) are wastes that contain or potentially contain material capable of causing infections in humans and that may pose a health risk to individuals or the community if not properly handled *(Standards for the Tracking and Management of Medical Wastes*, 40 CFR 22 and 259). Such wastes include cultures and stocks of infectious agents, pathological wastes (i.e., animal carcasses), blood, blood products and items contaminated with, blood and/or blood products, and wastes of exposed or potentially exposed animals. Sharps are also considered RMW and include objects, used or unused, which may penetrate the skin. Item considered sharps include syringes (with or without needles attached hypodermic needles, glass slides, cover slips, blood collection tubes and vials, test tubes, sharp metal objects, pipettes, and broken glass. In accordance with AFIP 40-12 sharps are placed into hard plastic leak-proof containers at

the site of their use. When the sharps containers are approximately three quarters full are sealed and autoclaved (Hadfield, 1995a).

Microbiological wastes (cultures and stocks of infectious agents) are kept separate from general waste and decontaminated prior to disposal (AFIP Regulation 40-12 by autoclaving or by chemical disinfection (bleach). Liquid wastes generated from BL-3 activities are collected in holding containers containing a solution of no less than 10 percent Clorox (bleach solution) or are collected into a container and autoclaved prior to drain disposal. Clorox or another suitable disinfectant is added to drains at the completion of work. Less than one gallon of Clorox-treated waste is discarded per week (Hadfield, 1995a).

Solid microbiological wastes generated in BL-3 laboratories are placed within double biohazard bags and rendered non-infectious by autoclaving. Chemical indicators are used to ensure that any infectious agent is completely destroyed. After being rendered noninfectious, this waste is disposed of as solid waste.

Solid waste generated in the conduct of BL-3 activities is rendered non-infectious by autoclaving prior to removal from the laboratory. After autoclaving,, this waste is placed into black plastic garbage bags and is discarded into a dumpster located at the rear of the AFIP. It is estimated that less than a box of such waste is generated weekly by the Brucella research project activities.

A Sterisä biological waste disinfection and waste reduction device is used to grind and decontaminate sharps and small quantities of liquid waste. This system processes and sterilizes wastes into a solid residue which may be discarded as general waste and a liquid waste which may be discarded into the local sewer system (Hadfield, 1995a; Suter, 1996). Sharps autoclaved in the BL-3 laboratories are also processed in the Steris unit.

RMW is placed into red, tear-resistant plastic bags. Bags containing RMW are placed into cardboard receptacles which are leak and puncture resistant and lined with plastic. In accordance with 29 CFR 1910.1030 *(Occupational Exposure to* Bloodborne *Pathogens* bags containing RMW are clearly labeled with the biohazard symbol and the words Regulated Medical Waste." In addition, the container is labeled with accumulation start date, origin of generation, point of contact and telephone number. RMW is not compacted.

Once bagged, RMW is stored in the department or division of origin or delivered to logistics division for storage in a holding area. Storage of packaged RMW does not exceed 7 days from the day of generation to the time of turn in. Bagged and boxed RMW is transported to the WRAMC loading dock holding areas for pick up by a certified commercial waste hauler under contract to the WRAMC. (Suter/Hadfield, 1996).

The AFIP Director of Logistics supervises the collection, transportation, and disposal of RMW. Departments and/or divisions ensure that each laboratory and/or activity

generating RMW develops a list of classes of RMW generated in the course of their work; ensures that RMW is correctly identified, properly packaged and transported the designated disposal site. Departments and/or divisions ensure that personnel potentially exposed to RMW are informed and trained regarding potential hazards and appropriate protective measures.

Handling and Disposal of Animal Wastes

Animal cages are changed in the laminar flow cabinets which are located within each room containing infected or potentially infected animals. This process involves transferring animals from dirty cages into clean cages. Dirty cages are then stacked five deep and placed inside biohazard bags. The bags containing the dirty cages and HEPA filtered bonnets and autoclave strips are autoclaved.. The autoclaved cages are then transported to the cage wash area (Hadfield,, 1995a).

Contaminated or potentially contaminated animal wastes (i.e., bedding and secretions) which have not been rendered non-infectious by chemical or physical means (e.g., autoclaving) are bagged in red biohazard bags, packed into cardboard boxes, sealed and collected by a certified biohazard waste handler under contract to the WRAIR for transport and incineration (Hadfield,, 1995a; Suter,, 1996). BDRP contaminated animal waste is rendered noninfectious by autoclaving and is then picked up by a certified biohazard waste handler for incineration. Pathological waste is frozen in morgue freezers
located in the Division of Laboratory Animal Medicine. Freezer storage for RMW does not exceed 30 days. Pathological waste is ultimately incinerated.

Handling and Disposal of Hazardous Chemicals

The *AFIP* Chemical Hygiene Plan (CHP) establishes responsibilities, policies, and procedures for handling chemicals and implements all relevant federal including DA and DoD, state, and local regulations. The AFIP CHP applies to all personnel working at the AFIP. The CHP details the minimal regulatory requirements for the safe use of hazardous chemicals and describes the use of engineering controls, work practices, and personal protective equipment. In accordance with AFIP CHP guidelines, SOPs are prepared for each operation involving the use of hazardous chemicals. Once prepared, SOPs are reviewed by the AFIP Safety Office and the AFIP Chemical Hygiene Officer (CHO). A hazard analysis is performed for each operation. SOPs are not approved until the AFIP Safety Officer conducts a preoperational survey to identify health, safety, and environmental issues. The frequency of subsequent, periodic surveys is at the discretion of the AFIP Safety Office. Chemical hygiene surveys are conducted yearly by WRAMC, Industrial Hygiene Section.

Requests for the purchase of hazardous chemicals are first reviewed by the CHO.. Chemicals are purchased in the smallest quantity appropriate for the planned activities. MSDSs for all chemicals used at the AFIP are maintained in the AFIP Safety Office and each work area maintains a file for chemicals unique to its area as well as for all hazardous

chemicals. Chemical storage, inventory, and labeling are conducted in accordance with guidelines described in the CHP.. Chemicals must be handled and stored in such a way that their identities are retained from initial receipt or production to use or ultimate disposal wherever feasible. Containers holding waste materials are labeled with the contents. Hazardous wastes are removed (turn-in) to the designated hazardous waste accumulation site. The CHP also describes implementation of the *AFIP Hazard Communication Program* (HAZCOM). Personnel working around hazardous chemicals attend annual HAZCOM Program training classes.

Personnel are provided with health and safety information including the contents of the *OSHA Laboratory Standard* (and appendices); the location and availability of the CHP;; Permissible Exposure Limits (PELs) for OSHA regulated substances; signs and symptoms associated with exposure to hazardous chemicals; and the location and availability of MSDSs in accordance with 29 CFR 1910.1045. In addition, personnel handling hazardous chemicals receive training annually regarding AFIP Regulation 385-10 (the *AFIP Safety Program) to* include details for the CHP,, *AFIP Safety Program,* methods to detect the presence of hazardous chemicals, chemical safety, hazardous waste minimization, physical and health hazards, and the use of engineering controls, work practices, and personal protective equipment.

The hazardous chemicals used as part of the BDRP-related activities at the AFIP include sodium hydroxide, methanol, hydrochloric acid, methyl tetra butyl ether, phenol, ethanol, acrylamide, ethidium bromide, and DNA synthesis reagents.

Chemical wastes are handled and disposed of in accordance with OSHA, the Environmental Protection Agency (EPA), DoD, DA, WRAMC, and AFIP directives and regulations in accordance with the AFIP CHP. AFIP employees must follow AFIP Regulation 40-12 *(Waste Management Program)* and AFIP Regulation 40-385 *(Safety Program).* Chemical wastes are stored in approved containers and labeled with their contents. Wastes are collected until they are fumed in to the WRAMC hazardous waste collection bunker located outside of Building 54. Hazardous wastes generated in the course of activities are not stored within the laboratory for more than 30 days (Hadfield, 1995a)

Hazardous chemical wastes generated by the BDRP-related activities at the AFIP are disposed of by a certified hazardous waste carrier contracted by the WRAMC. The WRAIR bills AFIP on a monthly basis for the removal of hazardous waste (Hadfield, 1995a).

Radioisotopes

Radioisotopes are not used in the conduct of BDRP activities at the AFIP (Hadfield, 1995a).

Toxins

Toxins are not used in the conduct of activities at the (Hadfield, 1995a).).

Human Subject

Research involving the use of human subjects is not conducted as part of BDRP activities at the AFIP Hadfield, 1 995a).

Animal Care and Use

Laboratory mice are used in the conduct of *Brucella* work at the AFIP. The AFIP animal facilities are fully accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) (Gonder, 1995). The AFIP Department of Infectious and Parasitic Diseases Pathology OI, *Infected Animals-Housing and Handling,* describes the housing, care, and handling of animals in accordance with Health and Human Services (HHS) Publication (CDC) 93-8395 and (NIH) 86-23 to maintain accreditation by AAALAC Protocols involving the use of animals are approved by the AFIP Laboratory Animal Care and Use Committee prior to initiation

All animal handlers and researchers are required to complete relevant training annually in accordance with AFIP Regulation 385-10. The AFIP Safety Office is responsible for monitoring training, maintaining written records of training completed, and ensuring that all topics required for a particular worker are addressed at least annually. The AFIP Safety Officer is responsible for ensuring that safety procedures are implemented and updated, as required. The Chief of the Division of Laboratory Animal Medicine reviews OIs involving safety for animal handlers and researchers and communicates suggestions for improvement to the AFIP Safety Committee.

Human Health and Safety

There are 15 workers involved in BDRP activities at the AFIP (10 from the WRAIR and 5 from AFIP), 10 of these individuals participate in BL-3 laboratory activities.. There are five workers who use the fourth floor laboratory on a regular basis and four workers using the laboratory on an irregular basis.

Persons at risk of acquiring infection or for whom infection would be unusually hazardous are not permitted to enter BL-3 laboratories or animal rooms. The laboratory director has final responsibility for determining who may enter or work within a given laboratory. The laboratory director is also responsible for establishing the policies and procedures which ensure that only those individuals advised of the potential hazards and who meet entry requirements may enter a laboratory or animal room (AFIP, 1 995b).

The AFIP Director ensures compliance with policies and standards specified by AFIP Regulation 40-12 The offices of Safety Management and Quality Assurance are

responsible for planning, directing, and evaluating the occupational health services required by AR 40-5 *(Preventive* for at risk of exposure to infectious and hazardous waste. The Office of Safety Management monitors work sites for compliance with applicable safety standards and is responsible for managing, controlling, and disposing of sharps for the AFIP.

AFIP employees with direct contact with animals and/or who segregate, store, package, transport, treat, or dispose of RMW receive training prior to commencing work and at least annually thereafter on RMW worksite policies and procedures. Written documentation of training is maintained by the AFIP Safety Officer.

Federal government and military personnel are offered hepatitis B vaccination through WRAMC Occupational Medicine in accordance with the *AFIP/ARC Bloodborne Pathogen Exposure Control Plan.* The Occupational Medicine Program retains vaccination status records of employees. When federal government or military employees are involved in an incident resulting in potential exposure to a bloodborne pathogen, they are required to immediately report to the WRAMC emergency room. The AFIP Safety Officer is notified within 24 hours of such incidents. The biosafety committee and safety officer investigate incidents of exposure. Employees with the potential of occupational exposure participate in training on an annual basis and whenever changes in procedures are made which may affect occupational exposure.

Brucellosis prevention includes reducing the exposure potential for employees, as well as serologic surveillance, diagnosis and treatment, and environmental protection in accordance with the AFIP Department of Infectious and Parasitic Diseases Pathology OI, *Occupational Health Plan for Brucellosis Prevention.* Employee exposure potential is reduced by adherence to the CDC/NIH Guidelines (1993) including facility design, engineering controls, and the use of personal protective equipment and special practices.

Serologic surveillance is mandatory for personnel involved with *Brucella* studies. Blood testing is used to test for the presence of antibodies to *Brucella* which would indicate an immune response from exposure. Blood samples are collected from personnel at risk of exposure prior to work in the laboratory and annually thereafter. Additional sampling may occur at any time at the request of the employee or the administration. A blood sample is drawn within 24 hours of a suspected occupational exposure. Personnel exhibiting positive antibody titers for *Brucella* are evaluated by Occupational Health Infectious Disease staff at WRAMC. ARP contract employees are evaluated by ARP occupational health contract physicians. Written documentation of testing and follow up care is maintained by the WRAIR and the AFIP Safety Office. Blood cultures (used to detect the presence of bacteria) are obtained as necessary for confirmation of positive serologic test results. Antibiotics therapy is initiated as treatment in the case of known or suspected exposures, as early diagnosis and prompt treatment reduce the possibility of long-term complications of infection.

Work with *Brucella* has been conducted at the AFIP since 1993. Since that time there have been four incidents where workers were suspected to have been exposed to live *Brucella.* Prompt antibiotic no cases of and occurred There have been no culture-confirmed cases of brucellosis at the AFIP since the initiation of the *Brucella* work in 1993. One worker, however, developed positive antibody titers, was treated and is being followed as a presumptive case of brucellosis (Hadfield,, 1995b).).

Training and Inspection

In January of 1993, prior to the onset of the *Brucella* research project BL-3 activities, the AFIP underwent a safety inspection by U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) facilities personnel. The inspectors evaluated renovations made to the AFIP HVAC systems, operational practices, and physical containment relevant to BL-3 facilities.. The inspection was conducted in accordance with the Basic Checklist for Biosafety Levels 1, *2,* and 3 *(32 CFR 627, Biological Defense Safety Program, Final Rule).* Physical aspects of the containment laboratory, room 4088, related procedures, policies and equipment were found to be in full compliance with the CDC/NIH guidelines for BL-3 containment(Hawley, 1993).

The inspectors also confirmed the adequacy of OIs for addressing microbiological safety, emergency situations, risk assessment, training, biocontainment laboratory operations, and laboratory procedures. Operational procedures were found to be in accordance with those required for BL-3 containment and microbiological practices, special practices, containment equipment, and laboratory and animal facilities were adequate for *Brucella* studies (Hawley, 1993).

Monthly safety inspections are conducted in accordance with AFIP Regulation 20-1. Reports of violations are forwarded to the party responsible for corrective action and to the safety officer for follow-up and monitoring. Annual laboratory inspections are conducted by the Quality Assurance Coordinator or designate. Laboratories are also inspected for compliance with College of American Pathology requirements. Safety issues revealed are forwarded to the safety officer.

Safety training includes job safety and health training appropriate to the work performed in accordance with AFIP Regulation 385-10. This includes an examination of the relevant safety standards as well as discussion of the material and equipment hazards associated with the worksite. Training also includes instruction regarding employee rights and responsibilities pursuant to relevant safety statutes, regulations and the Army *Safety* Program (AR 385-10). New employees receive safety training within 2 weeks of receiving work assignments. Initial training includes Command safety policy, department and/or division-specific safety information individual responsibility for safety and health, employee reporting procedures for hazardous operations/conditions, awareness of hazards specific to the individual's tasks, specialty or division, and first aid/CPR training where appropriate.

All laboratory personnel engaged in activities in BL-3 research laboratories must participate in mandatory training sessions at least annually in accordance with *BDRP Safety Training Manual*, the *WRAMC Exposure Control Plan*, the AFIP *Safety Manual*, and the Department of Infectious and Parasitic Diseases Pathology OI for *Microbiology Training for BL-2 and BL-3 Laboratories at the AFIP* Records of training are maintained by the AFIP Safety Office. Personnel working in BL-3 laboratories are required to annually attend training that includes organism-specific information; signs, symptoms, and exposure information; worker responsibilities; review of laboratory incidents; medical and environmental monitoring. Personnel engaged in work in BL-3 laboratories participate in a medical surveillance program requiring periodic blood samples. In addition, employee assigned to BL-3 laboratories must first demonstrate proficiency in handling infectious agents.

ALTERNATIVES CONSIDERED

The proposed action and subject of this EA is the continuance of the BDRP- *Brucella* research project at the AFIP in its present scope and size (Alternative 1, the Preferred Alternative). During the preparation of this E A two alternatives to the proposed action were identified. These alternatives include relocation of *Brucella* research project activities to a site other than the AFIP (Alternative 11); and the cessation of *Brucella* research project activities at the AFIP (Alternative 111, the No Action Alternative)

Alternative 1, the preferred alternative, is the continuance of the BDRP-funded Brucella research project at the AFIP as identified and described in the section of this EA entitled *Description of the Proposed Action.* The BDRP-funded *Brucella* activities are designed to research and develop a vaccine against a potential biological warfare agent. The preferred alternative supports the mission of the BDRP to protect U.S. military personnel from the effects of biological weapons.

Alternative 11 includes moving the BDRP-funded *Bruce/la* research project activities currently performed at the AFIP to another facility. Relocating the activities currently performed at the AFIP to another location would not significantly alter the environmental impact of the operations. In addition, the critical professional associations and collaborations currently existing among AFIP and WRAIR scientists would be lost. Alternative 11 is therefore not the preferred alternative

Alternative 111 (the No Action Alternative) includes cessation of the BDRP-funded *Brucella* research project. This is not the preferred alternative because cessation of these activities would eliminate the BDRP's contribution to the development of a human vaccine against *Brucella,* a potential biological warfare agent.

AFFECTED ENVIRONMENT

This section of the EA describes those aspects of the biophysical and socioeconomic environment that could be affected by the conduct of BDRP activities at the AFIP. The AFIP is located on the grounds of the WRAMC which is situated on approximately 114 acres in northern Washington, DC, an urban environment. The AFIP is a tenant of the WRAMC C and is located in Building 54.

To reduce redundancy with previous relevant documents and to meet the requirements of CEQ (40 CFR, Parts 1500-1508), this EA is tiered, in part, to earlier NEPA documentation. A detailed discussion of the affected environment of the AFIP can be found in the following documents: Environmental Science and Engineering (1984); reports by Kise Franks & Straw (1990a, 1990b); Rogers, Golden & Halpern (1990); and WRAIR (1993a, 1993b, 1994).

Plant and Animal Ecology

The AFIP is located in the oak-chestnut region of the Piedmont Plateau physiographic province. Tree species characteristic of this region are the white oak *(Quercus alba),* black oak *(Q. velutina),* tulip tree *(Liriodendron tulipifera),* smoothbark hickory *(Carya sp.),* chestnut oak (Q. *prinus),* scarlet oak (Q. coccinea), scrub pine *(Pinus virginiana),* and pitch pine (P. *rigida) (U.S.* Army Environmental Hygiene Agency, 1976). Wildlife of the region are characteristic of urbanized environments. Detailed descriptions of the wildlife species potentially inhabiting northern Washington, DC and discussions of the plant and animal ecology of the region are found in the WRAIR EAs (1993a, 1993b).

Geology

Washington, DC, is geographically divided by the Rock Creek into the Piedmont Province (west) and the Coastal Plain Province (east). AFIP lies east of the Rock Creek. The Piedmont Plateau is characterized by exposed metamorphic rocks, hilly to rolling terrain, and fast flowing streams. Major rock types include schist, medium- gneiss, biotite gneiss, and diorite (Soil Conservation Service, 1990; WRAIR, 1993a, 1993b). The WRAMC campus on which the AFIP is located is in the extreme eastern portion of the Piedmont Plateau physiographic province (Appalachian Highlands). The site is characterized by rolling hills varying in elevation from 74 meters to 107 meters above mean sea level. The land use patterns at the site (building and parking areas) result in generally flat terrain with a slight overall slope towards the south-southwest and the Rock Creek drainage system (Soil Conservation Service, 1990; WRAIR 1993a, 1993b).

Water Resources

The AFIP is located within the Rock Creek Drainage Basin. This major stream drains the entire with nearly all smaller streams eventually emptying into it (CH2M Hill, 1979). The Rock Creek originates in Montgomery County and terminates in the Potomac River. Surface water from the AFIP arising from precipitation drains through the WRAMC storm sewer system ("the Luzon tunnel, 2.44 by 1.67 meters, a tunnel which runs under the post from the intersection of Dahlia Street and Georgia Avenue to Rock Creek Park off the southwestern corner") (Environmental Science & Engineering, 1984) and eventually through the Washington, DC storm sewer system.

The AFIP lies above the Piedmont Hard Rock Formation (Maryland Office of Environmental Programs, 1986) which contain the most productive hard rock aquifers in the state. In general, the quality of the groundwater of the Piedmont Hard Rock Formation is good. Geologically, these formations are fractured non-calcareous rocks. Since the fractures are not extensively interconnected, the potential for groundwater contamination is moderate and any contamination is likely to be localized (Maryland Office of Environmental Programs, 1986). Groundwater resources are not used for drinking water purposes at the AFIP (WRAIR, 1993a).

Air Quality

The AFIP is located in Maryland Air Quality Control Area IV (Washington Metropolitan Area) which includes Montgomery County and Prince Georges County. The National Ambient Air Quality Standards (NAAQS) are incorporated into the standards set by the state agency. The State of Maryland incorporates the air quality standards implemented pursuant to the Clean Air Act. Citations include 40 CFR Parts 50, 51, 52, 57, 60, 61, 80, and 82. Subjects covered include ambient standards, new stationary sources, hazardous pollutants, and related topics.

The air quality of the Washington metropolitan area is generally good due principally to a lack of large industrial point sources within the region. Vehicular emissions are the major air pollutants in the Washington, DC, metropolitan area. Since 1985, ozone levels have periodically exceeded state standards. Pursuant to the Clean Air Act of 1990, the Washington metropolitan area was reclassified by the EPA as a serious non-attainment area for ozone because concentrations frequently exceed the NAAQS during warm weather months. Other monitored air pollutants have remained below standards set by the State of Maryland (Maryland Department of the Environment, 1989).

Cultural Resources

The Army Medical Museum collection was given the status of a National Historical Landmark in 1965. In 1990, the U.S. Army Corps of Engineers commissioned a cultural resources study of the WRAMC in compliance with Section 106 of the National Historic Preservation Act of 1g66 (as amended in 1980). This study identified the entire WRAMC installation as a potential National Register-eligible historic district, with the exception of the area north of Dahlia Street and east of 14th Street. Resources contributing to the status of this potential district included numerous building and landscape features. The study revealed no known archaeological sites and site examinations concluded that there was No chance. that preserved archaeological resources were located at the WRAMC site because of its history of development and land use patterns (Kise Franks & Straw, 1990a, 1990b).

Socioeconomic

The 1990 U.S. Census indicates that the population of Washington, DC included 249,034 households and 606,900 individuals. The median household income was S30,727 and 16.9 percent of all persons had incomes below the poverty level. Of employed persons over the age of 16, 17.0 percent were employed by the federal government. The median value of owner occupied housing units in 1990 was $123,900. Renter occupied housing units were 61.1 percent of all housing units.

ENVIRONMENTAL CONSEQUENCES

The BDRP-funded *Brucella* research project activities performed at the AFIP involve the use of *Brucella* species, which are capable of causing brucellosis, a disease affecting both animals and humans. Although rarely fatal, brucellosis can result in chronic adverse health effects if left untreated. Prompt antibiotic therapy administered following known or suspected exposure is effective in preventing acute and/or chronic disease. The risk to workers of laboratory-acquired infections is minimized by implementation of environmental engineering and work practice controls as described in the CDC/NIH publication entitled *Biosafety in Microbiological and Biomedical Laboratories* (1993), AR 385-69, and DA Pamphlet 385-69. Environmental engineering controls are in place at the AFIP to prevent *Brucella* organisms from contaminating the laboratory environment. Laboratory work practices employed reduce the likelihood of aerosol production during routine activities further reducing the risk of infection of laboratory workers. Work practice controls used to prevent contamination of the environment external to the BL-3 laboratories include regular disinfection of work surfaces, floors, and drains, and the segregation and autoclaving of waste materials, work clothes, and other materials prior to removal from the containment facilities.

In addition to the use of environmental engineering and work practice controls to reduce the risk of exposure to *Brucella,* a serosurveillance program is in effect to monitor workers and ensure that personnel are not infected subclinically with *Brucella.* Antibiotic therapy is immediately administered to workers with possible exposures. There has been one presumptive case of brucellosis in laboratory workers engaged in the conduct of BDRP-funded *Brucella* research studies at the AFIP. No incidence of secondary transmission of disease to those outside of the AFIP laboratory has been reported.

The risk to public health from the conduct of *Brucella* research at the AFIP is negligible. It is unlikely that the public would come into contact with viable *Brucella* originating from the AFIP BL-3 laboratories. The BDRP FPEIS concluded that releases of biological aerosols from BL-3 facilities were not reasonably foreseeable events. In order to generate sufficient force to produce an aerosol that could spread outside the BL-3 facility, an external catastrophic event, such as an airplane crashing directly on l the facility or an act of terrorism, must occur (BDRP FPEIS, 1989). The likelihood of such catastrophic occurrences is too small to be considered as reasonably foreseeable I (BDRP FPEIS, 1989). No such event has occurred in the more than 50 years in which the military has been conducting biological defense activities (BDRP FPEIS, 1989).

It is unlikely that an infected animal could breach the redundant barriers in place at the AFIP BL-3 animal facilities. Mice are housed in secure cages within closed laminar flow safety cabinets and BL-3 facilities are tightly sealed (e.g., doors, electrical outlets, ventilation equipment). In addition, there are no windows in Building 54. Mice used in *Brucella* studies are not a natural host for *Brucella* although they may be

capable of transmitting the disease to other animals via contaminated urine (Hadfield, 1 995b, 1995c).

The research methods, hazardous materials, and safety/containment practices employed in the conduct of the BDRP-funded work at the AFIP are consistent with those required and employed throughout the BDRP. There are no significant adverse environmental impacts associated with the continuation of the Brucella research project at the AFIP. Moreover, positive benefits to the health of U.S. civilians and military personnel will likely result.

The conclusions of this EA are based upon evaluation of the BDRP-funded *Brucella* research activities and any associated environmental impacts, potential adverse impacts resulting from cumulative effects, and an evaluation of the potential for the release of *Brucella to* the surrounding environment. In addition to the proposed action (Alternative 1), two other alternatives were considered. Alternative 11 includes conducting *Brucella* vaccine development studies at a location other than AFIP, and Alternative 111, the no action alternative. Implementation of any of the alternatives, including the preferred alternative, will not cause significant adverse environmental impacts. Alternatives 111 will not meet the needs of the national defense. The proposed action was evaluated after comparison with the suggested alternatives. It was concluded that the continuation of BDRP-funded *Brucella* research activities presents negligible adverse environmental impacts and has more positive attributes than other alternatives considered.

PERSONS AND AGENCIES CONTACTED

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Robert Weaver	CDC	(404) 639-3249

CONCLUSIONS

The principal conclusions of this are: 1) continuing the *Brucella* research activities, the preferred alternatives, will not result in a significant impact on the environment, 2) these activities will result in a significant benefit to the United States by protecting soldiers from the possible use of a potential biological warfare agent, and 3) moving these research activities to another location (Alternative II), or ceasing operations (Alternative III, No Action), will not significantly alter the environmental impact of this project

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LIST OF APPENDICES

MEMORANDUM OF UNDERSTANDING BETWEEN
ARMED FORCES INSTITUTE OF PATHOLOGY AND
WALTER REED ARMY INSTITUTE OF RESEARCH

SUBJECT: Support for Brucella Studies

1. Purpose. The Armed Forces Institute of Pathology (AFIP)and the Walter Reed Army Institute of Research (WRAIR) hereby enter into an agreement for Brucella studies.

2. Understanding

a. The recent Desert Storm war emphasized the need for vaccines against potential biological warfare agents. Production of these vaccines requires establishment of a suitable animal model and development of in vitro methods to screen potential vaccine candidates. This work requires use of Biosafety Level 3 (BSL-3)facilities which are not available at WRAIR.

b. Although the Division of Microbiology of the Department of Infectious and Parasitic Diseases Pathology performs many routine cultures on BSL-3 specimens and has an established BSL-3 laboratory and animal facilities current funding levels do not permit consultative or research services on BSL-3 organisms

c. WRAIR requests that AFIP provide a BSL-3 laboratory and BSL-3 animal care facility to house small laboratory animals for collaborative work with Brucella.

d. AFIP has a functional BSL-3 laboratory and BSL-3 animal care facility. Since Brucella studies require particular care to avoid infection of laboratory personnel and animal handlers, additional backup mechanisms are desirable to further enhance safety. WRAIR agrees to provide AFIP funding for microisolator cages, an autoclave suitable for sterilizing these cages, a backup air handling system, and an electronic monitoring system for the BSL-3 facilities.

e. Publications resulting from any collaborative research will not be submitted without approval of both parties and clearance through appropriate official channels. Publications and presentations by one party will include acknowledgment of the other party.

3. AFIP responsibilities

AFIP agrees to provide WRAIR with BSL-3 laboratory apace and BSL-3 laboratory animal facilities sufficient to perform collaborative studies with Brucella. These studies will include development of an animal model for challenge testing of vaccines, including establishment of diagnostic techniques for the presence and intensity of infection with the target organism and testing of vaccine candidates. Studies will also include development of in vitro assays to evaluate interaction of Brucella with cells or serum from infected animals. AFIP Will maintain facilities to meet all applicable regulatory requirements for BSL-3 facilities and, upon request, will provide documentation to that effect. AFIP will also ensure that collaborative scientific protocols have received appropriate approval for work with BSL-3 organisms. AFIP also agrees

APPENDIX A

MEMORANDUM OF UNDERSTANDING

to provide a senior investigator in the Division of Microbiology of the Department of Infectious Diseases and Parasitic Diseases Pathology to work in collaboration with investigators at WRAIR to develop, submit, supervise and publish results of protocols to be performed at AFIP.

4. WRAIR responsibilities.

a. WRAIR agrees to develop protocols in collaboration with investigator(s) at AFIP to establish models and use them for testing, and to provide candidate vaccines for testing.

b. WRAIR agrees to provide $177,000 in FY 92 to enhance facilities as noted 2(d) above. WRAIR further agrees to provide adequate funding for supplies, animals, and contractors to care for animals and provide other services directly related to the collaborative projects. The amount of this funding will depend on the nature and extent of projects developed by collaborators at WRAIR and AFIP.

5. Reference. WRAIR Brucella plan of 26 March 1992.

6. Effective Date. This agreement shall be effective upon signature of both parties and shall remain effective for five (5) years, unless terminated.

7. Amendments. This agreement may be revised at any time upon the mutual consent in writing of the parties concerned.

8. Termination. This agreement may be cancelled at any time by mutual consent of the parties concerned. This agreement may also be cancelled by either party upon giving at least 180 days written notice to the other party.

August J. Salvado
Colonel, MC
Director
Walter Reed Army Institute of Research

23 Sep 92
Date

Vernon W. Armbrustmacher
Colonel, USAF, MC
The Director
Armed Forces Institute of Pathology

20 Oct 92
Date

MEMORANDUM OF AGREEMENT
BETWEEN THE
WALTER REED ARMY MEDICAL CENTER
WALTER REED ARMY INSTITUTE OF RESEARCH
ARMED FORCES INSTITUTE OF PATHOLOGY
AND
DISTRICT OF COLUMBIA OFFICE OF EMERGENCY PREPAREDNESS

I. AUTHORITY AND PURPOSE. This Memorandum of Agreement (MOA) is executed in accordance with the requirements of Title 10, United States Code, Section 2370, in order to ensure effective fire, police and health emergency support services. This MOA documents the emergency support services to be provided by Walter Reed Army - Medical Center (WRAMC) and the District of Columbia Office of Emergency Preparedness to the Walter Reed Army Institute of Research (WRAIR) and the Armed Forces Institute of Pathology (AFIP) in the event of an accident or incident, or other emergency condition with Biological Defense Research Program (BDRP) agents, occurring at the facilities of the WRAIR and AFIP.

II. REFERENCES:

a. Title 10, United States Code, Section 2370.

b. 32 Code of Federal Regulations, Part 626 (Army Regulation 385-69, Biological Defense Safety Program.

c. Memorandum SGRD-UWZ-X, HQS, WRAIR, 25 January 1993, subject: Biological Defense Research Program (BDRP) Coordination with Local Support Authorities.

d. Telephone conversations between Colonel Kenneth E. Spencer and Ms. Pamela J. Thurber, Government of the District of Columbia (DC), Office of Emergency Preparedness various dates, subject: Biological Defense Research Program Coordination with Local Support Authorities.

e. Coordination meeting between representatives from the WRAIR (Colonel Kenneth E. Spencer - Executive Officer, LTC David Hoover - Division of Communicable Diseases and Immunology, Dr. Gary Matyas - Division of Biochemistry, and Mr. Bert Mueck Safety Office) and Government of the District of Columbia (Ms. Pamela J. Thruber - Office of Emergency Preparedness, Cpt Joe Herr - Acting Fire Chief, 8th Battalion, and Mr. Stefan Ventura Aide, 8th Battalion) on 28 January 1993, subject: Biological Defense Research Program Coordination with Local Support Authorities.

f. Walter Reed Army Medical Center Emergency Preparedness Plan, 1 July 1992.

g. Commanding General, WRAMC, Tenant Commanders' Meeting, January 1993.

APPENDIX B

h. Memorandum SGRD-UWZ-X, HQS, WRAIR, 11 February 1993, subject: Biological Defense Research Program (BDRP) Coordination with Local Support Authorities.

III. WALTER REED ARMY MEDICAL CENTER RESPONSIBILITIES:

a. Serve as host installation.

b. The Director, Plans, Training, Mobilization and Security (DPTMSEC) will provide the names, telephone numbers and locations of emergency responding officials to the DC Office of Emergency Preparedness, WRAIR and AFIP, in event of a mishap.

c. Provide the initial response i.e. fire, police, health services, etc. to a BDRP mishap at the WRAIR or AFIP and coordinate backup support from local community emergency officials as required.

d. Assume control of activities at the location of the mishap unless the D.C. Fire and Emergency Medical Services Department and/or its Hazardous Materials Response Unit has been called to assist in the response, in which case the incident is under the command of the senior ranking Fire Department responder. Upon mitigation of the incident, control of activities at the incident site will be returned to the Walter Reed Army Medical Center. -

e. Coordinate with the WRAIR Safety Office for special training or instruction required to handle BDRP agents for fire, Provost Marshal and health officials.

f. Coordinate with the WRAIR Safety Office on the scene of the mishap to determine if special equipment, other than normal operational equipment, is required to manage the BDRP mishap.

IV. WALTER REED Army INSTITUTE OF RESEARCH RESPONSIBILITIES:

a. Conform with regulatory and statutory guidelines concerning BDRP research.

b. Enforce Good Laboratory Practices at all times.

c. Ensure prompt notification to appropriate WRAMC emergency officials and, if appropriate, local emergency officials in event of a mishap.

d. Update names, telephone numbers and fax numbers of points of contact when a change occurs (encl 1). Specify who is responsible for emergency notification to WRAMC and/or District of Columbia emergency officials.

e. Provide information on the BDRP as well as information n the type of training necessary to provide an effective response.. Some training may be provided on a space available basis at no additional expense to the government.

f. Coordinate with the WRAIR Safety Office on the scene of mishap, to determine if special equipment, other than normal operational equipment of emergency responders, is required to manage] the BDRP mishap.

g. Report any BDRP incident not requiring a regulatory report, but in the professional judgment of the Director, WRAIR that could cause apprehension/alarm to the WRAMC installation or surrounding community, to the WRAMC and/or District of Columbia ace of Emergency Preparedness.

h. Make available to the WRAMC and District of Columbia office of Emergency Preparedness any BDRP information or reports which in its professional judgment, will assist the city in responding to public inquiries in the event of an emergency.

V. ARMED FORCES INSTITUTE OF PATHOLOGY RESPONSIBILITIES:

a. Conform with regulatory and statutory guidelines concerning BDRP research.

b. Enforce Good Laboratory Practices at all times.

c. Ensure prompt notification to appropriate WRAMC emergency officials and, if appropriate, local emergency officials in event of a mishap.

d. Provide to a list of names, telephone numbers and fax numbers to all signatories of this MOA. Specify who is responsible for emergency notification to WRAMC and/or District of Columbia emergency officials.

e. Report any BDRP incident not requiring a regulatory report, but in the professional judgment of the Director, AFIP, that could cause apprehension/alarm to the WRAMC installation o e surrounding community, to the WRAMC and the District of Columbia Office of Emergency Preparedness.

f. Make available to the WRAMC and District *of* Columbia Office of Emergency Preparedness any BDRP information or reports which in its professional judgment, will assist the county in responding to public inquiries in the event of an emergency.

VI. DISTRICT OF COLUMBIA OFFICE OF EMERGENCY PREPAREDNESS:

a. Coordinate provision of emergency response, i.e. fire, police, health officials etc. as requested by the WRAMC to manage - mishap.

b. Provide names, telephone numbers, and location for points of contact for fire, police, health officials, etc. to the WRAMC and WRAIR. Include the address where the emergency service is provided.

c. Provide the WRAMC, WRAIR and AFIP a copy of District of Columbia directives regarding city emergency operation procedures, to include reporting requirements. -

d. Coordinate with the WRAIR Safety Office on special training or instruction handling BDRP agents for emergency responding officials. This training will be oriented on the nature of BDRP agents and worse case scenarios.

e. Coordinate with the WRAIR special equipment required to handle BDRP agents for fire, police and health officials with the WRAIR.

VII. COORDINATION:

a. The WRAMC Safety Officer will be the primary official and the Director, Plans, Training, Mobilization and Security will be the alternate official during duty hours for coordinating emergency support to be provided pursuant to this MOA. After normal duty hours the primary official will be the WRAMC Administrative Officer of the Day.;

b. The WRAIR Safety Officer will be the primary official during duty hours, and the WRAIR Charge-of-Quarters will be the primary official during nonduty hours for coordinating emergency support to be provided pursuant to this MOA.

c. The AFIP Safety Officer will be the primary official during duty hours, and AFIP Charge-of-Quarters will be the primary official during nonduty hours for coordinating emergency support to be provided pursuant to this MOA.

d. The Shift Supervisor, Operations Division, Office of Emergency Preparedness, will be the primary and secondary official for coordinating emergency support to be provided pursuant to this MOA.

VIII. EFFECTIVE DATE, DURATION, PERIODIC REVIEW, AMENDMENT, TERMINATION:

a. This MOA becomes effective on the date of the last signature thereto, and remains in effect for five years thereafter.

b. The coordinating officials will jointly review this MOA on its annual anniversary and document the results of their review.

c. Additions and deletions to the terms and conditions of this MOA will be executed in writing by the signatories. Amendments which alter material terms and conditions of this MOA still be executed in writing by the signatories. Amendments which o not alter material terms and conditions (e.g., changes in coordinating officials), or which explain, interpret, or clarify the meaning of a material term and condition, may be done by an, exchange of letters, at the coordinating official level.

d. This MOA may be revoked and canceled, by either party, upon 180 days' written notice.

Signature Date
RONALD R. BLANCK
Major General, Medical Corps
Commander, Walter Reed Army
Medical Center
Washington, DC 20307

Signature Date
VERNON W. ARMBRUSTMACHER
Colonel, Medical Corps
Director
Armed Forces Institute of Pathology
Washington, DC 20306-6000

Signature Date
AUGUST J. SALVADO
Colonel, Medical Corps
Director, Walter Reed Army
Institute of Research
Washington, DC 20307

Signature Date
STEPHEN RICKMAN
Office of Emergency Preparedness
2000 14th Street, N.W.
Washington, DC 20009

EMERGENCY TELEPHONE NOTIFICATION
Walter Reed Army Institute of Research,
WRAMC
Washington, DC

	Work	Home	Fax
1. Safety Office	202-576-3019		202-576-3114
2. Charge-of-Quarters	202-576-6333		202-576-3114

NOTE: The "576" telephone exchange listed above has been changed since this agreement was finalized. The new exchange is "782." The Safety Office may also be reached at (202) 782-0955.

AFIP
CPS-M
Washington D.C.

Department of Infectious and
Parasitic Diseases Pathology -
30 January 95

BIOCONTAINMENT LABORATORY OPERATIONS
Biosafety Level 3

1. PURPOSE: To provide policies for safe operation of the biosafety level 3 laboratory and animal quarters.

2. ASSIGNMENT OF EMPLOYEES:

a. The Project Sponsor Division Chief and Chairman, Biosafety Committee will assure only physically sound and mentally stable personnel are assigned to the BL-3 biocontainment laboratories.

b. Women assigned to containment laboratories are required to notify their Division Chief as soon as Pregnancy is suspected *so* that any risk can be avoided. Pregnant women will be assigned duties outside of a containment laboratory. Transfer to other areas will be arranged by the Division Chief in coordination with the Resource Management Office (for federal employees) and ARP (for ARP employees).

c. Division Chiefs will assign a safety representative or NCOIC to inspect or survey each containment suite monthly. The report will be signed and forwarded to the AFIP safety officer through the Division Chief.

d. The AFIP safety officer and a Biosafety Committee representative will inspect or survey the BL-3 facilities quarterly, using the checklists found in attachment 2.

3. AUTHORIZATION FOR ADMITTANCE

a. Only authorized and required personnel shall be admitted to the BL-3 areas. Authorized persons are those required on the basis of program or support need. Such persons will be made aware of the potential hazards and will comply with all entry and exit procedures as described herein.

b. Supervisors are responsible for insuring appropriate safety orientation and training is conducted for each new employee whose duties require entry into biocontainment areas. The supervisor will ensure the employee attends the biocontainment orientation. Documentation of training for each employee will be maintained by the safety office. This will include a mandatory reading of this regulation and an orientation by the supervisor or his designated representative in the general practices, procedures and techniques in the containment laboratories. Orientation on

APPENDIX C

general techniques is to be accomplished prior to first entry into biocontainment areas.

1. Training in general techniques and unique techniques to a specific area is the responsibility of the supervisor and will include as appropriate:

(a) Personal emergency procedures: Personnel assistance alarms, communication equipment, fire alarms, emergency gas shutoff, and procedures during and after normal duty hours.

(B)Operations in class II biological safety cabinets, i.e. types of cabinets and procedures within the cabinets (i.e. pipetting, disposal of infectious material, and clean up).

(c) Use of syringes with infectious material, the disposal and transport of syringes from cabinets to animal rooms, how to expel from loaded syringes or, how to safely remove a needle from the syringe, and procedures for inoculation of animals with infectious material.

(d) Centrifugation procedures: use of sealed rotors and tubes, safety cups, emergency shut-off and clean up.

(e) Orientation program on the Occupational Safety and Health Administrations Hazard Communication Standard(29 DFR 1910.1200).

(f) Use of disinfectant traps and HEPA filters on vacuum lines (portable vacuum pumps).

(g) Management of accidents (animals bites, self-inoculation with needles, infectious spills inside and outside biological safety cabinets, centrifuge accidents, etc.).

(h) Autoclave operation and preventative maintenance.

(i) Use and operation of laminar flow animal housing systems.

(j) Handling of compressed gasses.

(k) Disinfection policy for removal of non-autoclaved items from biosafety level three areas.

2. AFIP Personnel:

(a) will be immunized as required by the Biosafety Committee and or the Division Chief for the Project. Immunization requirements will be the more stringent set if disagreement occurs.

(b) Prior to entry into a containment suite, immunization or baseline skin tests, medical or serological examination as prescribed for the particular infectious agents in use, must be completed. All personnel will be screened for the following as needed:

(1) Medical history for personnel assigned to BL-3 areas.
(2) Respiratory protection program if required
(3) Auditory screening and use of ear protection if required.
(4) Radiation protection program if working with isotopes.
(5) Use of safety glasses or shields.
(6) tuberculosis surveillance program if required
(7) immunocompetency evaluation as required

(C) Personnel seeking entrance to a containment suite to which they are not regularly assigned may enter only if there is a valid

reason for the visit, they are properly immunized or protected against agents currently in use, and have prior approval from the Division Chief responsible for the containment area.

(D) Other personnel will not enter any room of any BL-3 area which will be posted with a biohazard sign.

(E) Personnel involved with BL-3 activities who are scheduled to terminate their service will not enter a containment area within 14 days Prior to separation or transfer.

3. Other personnel:

(a) Visitors, service and contractor personnel must have approval prior to entrance and be adequately protected from exposure to infectious substances. "Adequately protected" is interpreted to mean:

(1) the visitor enters only the "clean" areas of the building; or

(2) Before admittance to a BL-3 area, base line skin tests, medical or serological examination, as prescribed for the agents in use, will have been completed, and training in personal protective clothing and equipment has been provided or

(3) if 2 is not complete and admission is required, then:

(a) When authorized maintenance personnel must enter a containment area, warning will be given of any unusual situation that may be hazardous, such as spills or leaks

(b) the visitor will be accompanied by the principle investigator to evaluate the scope of the repair. If repair can be accomplished easily in protective clothing with a minimal risk of exposure, the repair may proceed.

(c) If repair is not easy and safe to accomplish in personal protective clothing, the area will be evacuated, infectious work will be suspended, decontamination performed, and the area declared "clean".

4. SIGNS

a. Biohazard signs will be posted on entry doors and change room doors to containment areas: AUTHORIZED PERSONNEL ONLY"

The signs will be covered or removed if the area has been decontaminated and certified as such by the safety officer AFIP.

b.. An up-to-date list of all immunizations required for entry into the suite and the name and telephone number of a responsible individual will be posted.

c. The universal biohazard sign will be posted on the entry door to the "clean" change room.

d. The entry doors to the BL-3 areas will have the following sign posted:

BIOSAFETY LEVEL 3 AREA

A wrap-around gown (not a lab coat) worn over street clothing and laboratory shoes or shoe covers must be worn at all times in the suite and will be left within the suite upon exiting. Exit showers

are not required.

5. ENTRY AND EXIT PROCEDURES

A. Personnel entering a suite designated BL-3, as indicated by a sign posted on the entry door, will wear a wrap around water repellent gown (not a laboratory coat) over street clothing or scrubs, mask and gloves at all times within the suite. The gown is left within the suite upon exiting and can be reused if not contaminated. Exit showers are not required when leaving these designated areas, but hands will be washed prior to exit.

B. Only laboratory shoes (work shoes or sneakers) will be worn inside contaminated suites. "Work shoes" will not be worn outside the BL-3 areas. Shoe covers will be provided for visitors and maintenance personnel. Footwear will be left in the "contaminated' area after completion of work. Shoes are stored on appropriate shelves.

C. (1) Color coded laboratory clothing is authorized for wear inside containment suites and BL-2 areas. "Red" scrubs may be obtained in the clean area locker room. A wrap around gown is also available in the locker room or just inside the BL-3 area. When departing, the wrap around gown is discarded if contaminated but may be reused if not contaminated. Gowns will be changed at least weekly. After removal of the gown, gloves, mask, etc. you may proceed into the change room. Scrubs may be used multiple times. At least weekly scrubs are discarded into the laundry sack.

(2) Eyeglasses and any jewelry worn in containment areas must be washed off with disinfectant or worn during hand washing prior to leaving the area.

6. PERSONAL OPERATIONS (Smoking. Drinking, etc.)

a. Smoking is prohibited within all AFIP facilities. Consumption of foods and beverages is prohibited within the containment areas.

b. Removal of items from the containment area. Items leaving the containment should be thoroughly disinfected or sterilized. Autoclaving is required for nonessential items. A bleach dip or the equivalent is required for the outer surface of tubes, or other such items containing samples, cultures, etc.

8. EQUIPMENT AND SUPPLIES

a. All equipment items will be decontaminated before being removal from a BL-3 area. The person accomplishing the decontamination, his phone number, the method used, the date, and the agent will be entered on a tag. Surface decontamination with an effective disinfectant is acceptable.

b. equipment known to be or suspected to be faulty will not be operated. Mechanically unsafe equipment will be tagged immediately and reported to medical maintenance.

c. Equipment to be serviced will be adequately decontaminated

and, if feasible, removed from containment areas.

d. regulators, valves, connections, etc., for compressed gas cylinders and equipment using compressed gases will not be lubricated.

e. The use of electric incinerators is encouraged in the BL-3 areas. Open flames of any type will not be left unattended. Burners will be turned off completely before departure from the BL3 contaminated laboratory area. If a gas line supplies the area, the gas will be turned off at the bench valve. The pilot light will not be left on overnight.

f.. Supplies and equipment will be uncrated in the "clean" areas to avoid the necessity of decontaminating empty cartons, boxes, and packing materials.

9. FLAMMABLE LIQUIDS

a. Flammable liquids will be stored in "explosion proof" refrigerators only if the flash point is above the refrigerator temperature

b. Ethyl ether will be stored on well ventilated shelves and not in refrigerators.

c. Flammable liquids from containment suites will not be disposed of by autoclaving or by pouring into building drains, but will be collected in decontaminated containers to be disposed of in accordance with AFIP hazardous waste regulation (reg #).

10. REGISTRATION. STORAGE AND TRANSPORT OF INFECTIOUS ORGANISMS

a. All work involving infectious organisms must be approved by the biosafety committee. All organisms requiring BL-3 facilities must be registered with the biosafety committee and approved by the AFIP safety officer and administration.

b. BL-3 infectious or toxic materials may be stored in refrigerators, incubators or freezers which are marked with the universal biohazard sign.

c. All infectious or toxic materials stored in refrigerators or freezers must be properly labeled and stored in containers capable of withstanding the thermal shock of freezing and thawing.

d. When work is completed, all infectious cultures or toxins will be removed from work benches and cabinets and stored in a designated refrigerator or freezer. If materials are to be discarded, they will be placed in appropriate disinfectant or autoclaved.

e. Glassware containing infectious liquids should be autoclaved or decontaminated as soon as possible and definitely before transport to glassware facilities.

f. Organisms designated for long-term storage will be maintained in locked freezers.

g. Primary containers of infectious or toxic substances for transfer between containment suites will be placed in a secondary, unbreakable container with solid sides and bottom and a tight cover, and surface decontaminated. The secondary container will be labeled: "Infectious Material - Do not open" The name of the sender and the destination of the container must be included on the label if it is leaving the Institute.

h. Infectious, toxic or recombinant materials will be shipped off-post in accordance with Federal Regulations (CDC, Fed Reg).

Division Chief approval is required prior to shipment. Shipment of BL-3 organisms/toxins must be approved by the Director, AFIP before shipment.

11. LABORATORY TECHNIQUES

a. General Techniques

(1) Biological safety cabinets will be used whenever possible for all procedures with infectious organisms. Work involving viable BL-3 containment level organisms will not be conducted in open vessels or an open bench, unless personnel are wearing the proper safety equipment.

(2) Latex or plastic examination gloves must be worn when handling infected animals or infectious or toxic materials. An appropriate disinfectant will be available for surface decontamination of gloves within the safety cabinet.

(3) The careful performance of certain laboratory procedures must be emphasized because some procedures can generate small particle aerosols. Those procedures, when used with highly infectious (BL-3) organisms or toxins, will be confined to biological safety cabinets. Such procedures include, but are not limited to (a) high speed blending, mixing and grinding, (b) agitation, (c) centrifugation in unsealed table-top centrifuges, (d) sonication, and opening vials of lyophilized cultures.

(4) All employees working with infectious or toxic materials will adopt the habit of keeping their hands away from their mouth, nose, eyes and face so as to minimize self inoculation.

(5) Doors to all microbiological laboratories and rooms housing infected animals will be closed at all times except for necessary entry and exit.

(6) Disposable items should be used whenever possible.

(7) Sharps use should be held to a minimum and disposable replacement items should be used whenever possible (i.e. disposable tissue grinders).

(8) All work surfaces must be decontaminated after use, and immediately following any spill or release of infectious material.

(9) Eye protection will be worn with procedures involving a splash hazard such as, but not limited to, inoculation of animals with infectious material, and necropsy of infected animals.

b. Pipettes:

(1) Mouth pipetting is prohibited in all laboratories. Mechanical pipetting devices will be used. Any pipetting manipulations which may result in the formation of infectious aerosols must be done in a biological safety cabinet.

(2) Pipettes used for infectious or toxic materials will be plugged with cotton.

c. Syringes:

(1) A luer-lock hypodermic syringe will be used whenever possible.

(2) The use of syringes for making dilutions is discouraged. Whenever feasible, dilutions for plating, tissue culture inoculation, etc., will be made in capped plastic tubes using a mechanical pipetter.

(3) It is advisable to use an alcohol soaked pledges about the needle and stopper when removing a syringe and needle from a diaphragm-sealed vaccine bottle containing infectious material.

(4) Whenever practical, needles will not be removed from syringes or multi-draw adapters and the needle covers will not be replaced after removal. However, when necessary, needle covers can be replaced with hemostats or needle nosed pliers. Needles can be removed with hemostats or needle-nosed pliers when necessary.

d. Centrifuges:

(1) Sealed centrifuges will be used for centrifugation of infectious substances within the BL-3 laboratory. Sealed rotors and cups are encouraged. In the case of sealed cups, the cups will be opened in a safety cabinet following centrifugation.

(2) Before centrifugation, check tubes for cracks, inspect the side of the cup for rough walls caused by corrosion or adhering matter, and ensure that the rubber cushions are clean and properly seated.

(3) Avoid decanting centrifuge tubes. If absolutely necessary, wipe off the outer rim with a disinfectant; otherwise, the infectious fluid will spin off as an aerosol. Avoid filling the tubes intended for angle rotors to the point where fluid will reach the rim of the tube under horizontal centrifugal force, except in designated centrifuge bottles. Centrifuge tubes should only be filled to the maximum limit set by the manufacturer of the centrifuge, rotor, and/or tubes.

(4) All personnel will be instructed by their supervisor in the operation, safety and maintenance of centrifuges prior to being authorized to use such equipment.

References:

1. Biosafety in Microbiological and Biomedical Laboratories 3rd edition CDC/NIH Guidelines. U.S. Government Printing Office, Washington DC 1993.

Reviewed by

Ted L. Hadfield, LTCOL, USAF, BSC
Chief, Division of Microbiology

FINDING OF NO SIGNIFICANT IMPACT

ENVIRONMENTAL ASSESSMENT

Biological Defense Research Program
at the Armed Forces Institute of Pathology

1. PROPOSED ACTION: The proposed action and subject of the Environmental Assessment (EA) is the continuation of the Biological Defense Research Program (BDRP) Brucella research project at the Armed Forces Institute of Pathology (AFIP) located in Washington, DC (Alternative I). The objective of these research activities is to develop an effective human vaccine for Brucella, a potential biological warfare agent. A vaccine to prevent brucellosis in humans does not currently exist. This EA is tiered, in part, to the BDRP Final Programmatic Environmental Impact Statement (FPEIS) (1989).

2. ALTERNATIVES CONSIDERED: The preferred alternative (Alternative I) is to continue *Brucella* research activities at the AFIP. Two alternatives in addition to the proposed action are considered. Alternative II includes conducting *Brucella* vaccine development studies at a location other than the AFIP and Alternative III, the No Action alternative (cease the BDRP *Brucella* research project at AFIP). Alternative III does not meet the needs of the national defense.

3. ENVIRONMENTAL CONSEQUENCES AND MITIGATION MEASURES: This project is conducted in a Biosafety Level 3 (BL-3) laboratory, where extensive procedural, engineering, and health/safety practices exist to ensure that workers are protected, and that the *Brucella* organism is completely contained within the laboratory. The BDRP FPEIS concluded that the likelihood of a catastrophic accident releasing the organism outside the BL-3 facility is considered too small to be a reasonably foreseeable event.

4. FACTORS CONSIDERED IN THE FINDING OF NO SIGNIFICANT IMPACT: The EA systematically reviews the nature of the proposed action and associated risks and issues. Particular attention is given to adverse environmental impacts to worker and public health consequences associated with research activities involving *Brucella*, an infectious bacterium. Feasible alternatives with regard to needs of the United States and the U.S. Army and potential adverse effects on the environment are evaluated.

5. CONCLUSIONS: The principal conclusions of this EA are: 1) continuing the *Brucella* research activities, the preferred alternative, will not result in a significant impact on the environment, 2) these activities will result in a significant benefit to the United States by protecting soldiers from the possible use of a potential biological warfare agent, and 3)

moving these research activities to another location 11), or ceasing operations (Alternative 111, No Action), will not significantly alter the environmental impact of this project

FOR THE COMMANDER:

_____ _____

CHRISTINE M. GALANTE, COL, AN DATE
Deputy Chief of Staff for Regulatory Compliance and Quality
U.S. Army Medical Research and Materiel Command

Comments on this Finding of No Significant impact may be directed to Commander, USAMRMC, ATTN: MCMR-PA (Charles Dasey), Fort Detrick, Frederick, MD 21702 and must be received by May 23, 1996. Copies of the EA are available at the Martin Luther King Memorial Library, Sociology, Education and Government Section 901 G Street, N.W., Washington, DC, 20001 and the Shepard Park Library 7420 Georgia Avenue, N.W., Washington, DC, 20307.